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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/504,389	02/15/2000	Mark W. Perlin	PERLIN-8	7829

7590 05/21/2002
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EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/21/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/504,389

Applicant(s)

PERLIN, MARK W.

Examiner

Brusca S John

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The instant application has been reassigned to a new examiner.
2. The papers received on 01 March 2002 have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process. The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

COPY OF PAPERS

ORIGINALLY FILED

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

3. It is brought to the Applicant's attention that the marked up version of claim 17 in the amendment received 01 March 2002 did not include the deletion of the phrase "the DNA mixture" and the marked up version has been corrected by informal examiner's amendment to do so.

Drawings

4. The formal drawings received with the amendment filed 01 March 2002 have been entered into the specification.

Claim Rejections - 35 USC § 112

5. The rejection of claims 17-22 under 35 U.S.C. § 112, second paragraph in the Office action mailed 21 August 2001 is withdrawn in view of the arguments and amendment filed 01 March 2002.

6. The rejection of claims 17-22 under 35 U.S.C. § 112, first paragraph in the Office action mailed 21 August 2001 is withdrawn in view of the arguments and amendment filed 01 March 2002.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17-30 are indefinite for recitation of the phrase in part (a) of claim 17 “obtaining DNA profile data that include a mixed DNA sample” because it is not clear whether the phrase refers to data or DNA molecules. The rejection would be overcome by amending claim 17 to recite “obtaining DNA profile data of a sample that comprises the DNA mixture.”

Claim Rejections - 35 USC § 102

8. The rejection of claim 17 under 35 U.S.C. § 102(b) as being anticipated by Menchen et al. or Grossman in the Office action mailed 21 August 2001 is withdrawn in view of the arguments and amendment filed 01 March 2002.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 17-22, 24, 25, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Perlin et al.

The claims are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules. The method utilizes a mathematical procedure comprising linear equations. In some embodiments the method is limited to DNA molecules obtained by a process of polymerase chain reaction of a short terminal repeat locus. In some embodiments the mathematical analysis includes a matrix or vector representation of the linear equations. In some embodiments the method includes an optimization step.

Perlin et al. shows on pages 1200-1204 a mathematical method of analysis of a mixture of stutter DNA molecules generated by polymerase chain reaction of a short terminal repeat locus. Perlin et al. shows that it is possible to determine the genotype of a DNA molecule in the mixture by application of the method. The mathematical method comprises a matrix-vector analysis. Perlin et al. shows methods of determining the optimum solution to obtain the correct genotype.

11. Claims 17, 18, 20, 22-24, and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill et al.

The claims are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules. The method utilizes a mathematical procedure comprising linear equations. In some embodiments the method is limited to DNA molecules obtained by a process of polymerase chain reaction of a short terminal repeat locus. In some embodiments the DNA mixture comprises DNA derived from different individuals. In some embodiments the genotype is chosen from a database of genotypes. In some embodiments the database of genotypes includes a genotype of a perpetrator of a crime In some embodiments the method includes an optimization step.

Gill et al. shows throughout a mathematical method of analysis of a mixture of DNA molecules generated by polymerase chain reaction of a short terminal repeat locus from different individuals. Gill et al. shows that it is possible to determine the genotype of a DNA molecule in the mixture by application of the method. The mathematical method comprises the use of linear equations. Gill et al. shows in figure 1 methods of determining the optimum solution to obtain the correct genotype. Gill et al. shows selection of the correct genotype from a database of possible genotypes. Gill et al. provides guidance on pages 51-53 to use the method for forensic analysis of samples to determine whether DNA of a suspect is present in a sample.

12. Claims 17, 18, 20, 22-24, and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Evett et al.

The claims are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules. The method utilizes a mathematical procedure comprising linear equations. In some embodiments the method is limited to DNA molecules obtained by a process of polymerase chain reaction of a short terminal repeat locus. In some embodiments the DNA mixture comprises DNA derived from different individuals. In some embodiments the genotype is chosen from a database of genotypes. In some embodiments the database of genotypes includes a genotype of a perpetrator of a crime. In some embodiments the method includes an optimization step.

Evett et al. shows throughout a mathematical method of analysis of a mixture of DNA molecules generated by polymerase chain reaction of a short terminal repeat locus from different individuals. Evett et al. shows that it is possible to determine the genotype of a DNA molecule in the mixture by application of the method. The mathematical method comprises the use of linear

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equations. Evett et al. shows on page 63 a method of calculating the likelihood ratio for a genotype. Evett et al. shows selection of the correct genotype from a database of possible genotypes. Evett et al. provides guidance on pages 62-63 and throughout to use the method for forensic analysis of samples to determine whether DNA of a suspect is present in a sample.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 17, 18, 20, 22-24, and 26-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-8, and 11 of copending Application No. 09/779096 in view of Gill et al. or Evett et al.

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This is a provisional obviousness-type double patenting rejection.

The instant claims are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules. The method utilizes a mathematical procedure comprising linear equations. In some embodiments the method is limited to DNA molecules obtained by a process of polymerase chain reaction of a short terminal repeat locus. In some embodiments the DNA mixture comprises DNA derived from different individuals. In some embodiments the genotype is chosen from a database of genotypes. In some embodiments the database of genotypes includes a genotype of a perpetrator of a crime. In some embodiments the method includes an optimization step.

Claims 1, 6-8, and 11 of copending Application No. 09/776096 are drawn to a method of analyzing the genotype of a mixed, amplified DNA sample, methods of determining the confidence of the determination, and use of the method to identify suspected criminals. The claims are not drawn to method utilizing a mathematical procedure comprising linear equations.

Gill et al. shows throughout a mathematical method of analysis of a mixture of DNA molecules generated by polymerase chain reaction of a short terminal repeat locus from different individuals. Gill et al. shows that it is possible to determine the genotype of a DNA molecule in the mixture by application of the method. The mathematical method comprises the use of linear equations. Gill et al. shows in figure 1 methods of determining the optimum solution to obtain the correct genotype. Gill et al. shows selection of the correct genotype from a database of possible genotypes. Gill et al. provides guidance on pages 51-53 to use the method for forensic analysis of samples to determine whether DNA of a suspect is present in a sample.

Evet et al. shows throughout a mathematical method of analysis of a mixture of DNA molecules generated by polymerase chain reaction of a short terminal repeat locus from different individuals. Evet et al. shows that it is possible to determine the genotype of a DNA molecule in the mixture by application of the method. The mathematical method comprises the use of linear equations. Evet et al. shows on page 63 a method of calculating the likelihood ratio for a genotype. Evet et al. shows selection of the correct genotype from a database of possible genotypes. Evet et al. provides guidance on pages 62-63 and throughout to use the method for forensic analysis of samples to determine whether DNA of a suspect is present in a sample.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of claims 1, 6-8, and 11 of copending Application No. 09/776096 by use of linear equations because Gill et al. and Evet et al. show mathematical methods utilizing linear equations that perform the method of the copending claims.

15. Claims 17-22, 24, 25, 29, and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 8 of copending Application No. 09/779096 in view of Perlin et al.

This is a provisional obviousness-type double patenting rejection.

The instant claims are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules. The method utilizes a mathematical procedure comprising linear equations. In some embodiments the method is limited to DNA molecules obtained by a process of polymerase chain reaction of a short terminal repeat locus. In some embodiments the mathematical analysis includes a matrix or vector representation of the linear equations. In some embodiments the method includes an optimization step.

Claims 1, 6, and 8 of copending Application No. 09/776096 are drawn to a method of analyzing the genotype of a mixed, amplified DNA sample, methods of determining the confidence of the determination, and use of the method to identify suspected criminals. The claims are not drawn to method utilizing a mathematical procedure comprising linear equations, or use of matrix or vector analysis.

Perlin et al. shows on pages 1200-1204 a mathematical method of analysis of a mixture of stutter DNA molecules generated by polymerase chain reaction of a short terminal repeat locus. Perlin et al. shows that it is possible to determine the genotype of a DNA molecule in the mixture by application of the method. The mathematical method comprises a matrix-vector analysis. Perlin et al. shows methods of determining the optimum solution to obtain the correct genotype.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of claims 1, 6, and 8 of copending Application No. 09/779096 by use of the matrix vector linear equation analysis of Perlin et al. because Perlin et al. shows that their method allows for analysis of the genotype content of a mixed DNA sample.

Conclusion

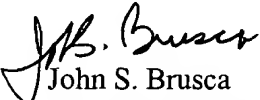
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M_F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.


John S. Brusca
Primary Examiner
Art Unit 1631

jsb
May 17, 2002